This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of the Claims:

1. (Currently Amended) A method of treating colon cancer or rectal cancer which comprises administering to a patient in need of ~~such~~ said treatment an ~~a therapeutically effective~~ amount of irinotecan, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, and an ~~a therapeutically effective~~ amount of thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, wherein the amounts of irinotecan and thalidomide are effective to treat colon cancer or rectal cancer.

2. (Original) The method of claim 1 wherein the cancer is primary or metastatic.

3. (Previously Amended) The method of claim 1 wherein the irinotecan, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 25 to about 750 mg/m^2, and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

4. (Previously Amended) The method of claim 3 wherein the irinotecan, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 500 mg/m^2, and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

5. (Previously Amended) The method of claim 4 wherein the irinotecan, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 350 mg/m^2, and the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

6. (Currently Amended) A method of reducing a dose-limiting adverse effect associated with ~~increasing the dosage of~~ irinotecan ~~that can be safely and effectively administered to a patient~~, which comprises administering to a patient in need of said reduction ~~such an increased dosage~~ an amount of thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, that is sufficient to reduce the ~~a~~ dose-limiting adverse effect ~~associated with the irinotecan~~.

7. (Previously Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered prior to the administration of the irinotecan.

8. (Previously Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered simultaneously with the administration of the irinotecan.

9. (Previously Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered after the administration of the irinotecan.

10. (Original) The method of claim 6 wherein the dose-limiting adverse effect is selected from the group consisting of early-forming diarrhea, late-forming diarrhea, nausea, vomiting, anorexia, constipation, flatulence, leukopenia, anemia, neutropenia, asthenia, abdominal cramping, fever, pain, loss of body weight, dehydration, alopecia, dyspnea, insomnia, and dizziness.

11. (Original) The method of claim 10 wherein the dose-limiting adverse effect is early-forming diarrhea or late-forming diarrhea.

12. (Previously Amended) The method of claim 6 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 2000 mg.

13. (Previously Amended) The method of claim 12 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

14. (Previously Amended) The method of claim 13 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

15. (Previously Amended) The method of claim 14 wherein the thalidomide, or pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

16. (Currently Amended) A method of increasing the therapeutic efficacy of irinotecan which comprises administering to a patient in need of ~~such~~ said increased therapeutic efficacy an amount of thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, that is sufficient to increase the therapeutic efficacy of irinotecan.

17. (Previously Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered prior to administration of the irinotecan to the patient.

18. (Previously Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered during administration of the irinotecan to the patient.

19. (Previously Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof, is administered after administration of the irinotecan to the patient.

No fee is believed to be due for this response. However, if any fees are required to enter this response into the file of the application and/or to avoid abandonment of the application, please charge such fees to Pennie & Edmonds LLP's Deposit Account No. 16-1150.

Respectfully submitted,

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